

### **REMARKS**

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks. No new matter is introduced by the foregoing amendments, as support for such can be found in, at least, paragraph [0029] of the specification and the original claims.

#### ***Objection to the Claims***

At page 2 of the Office Action, Claim 30 was objected to because it allegedly is in improper dependent form for failing to limit the subject matter of a previous claim. Applicants respectfully request reconsideration of this objection.

Claim 30 has been canceled without prejudice.

For at least the foregoing reasons, Applicants respectfully submit that the objection is moot, and Applicants respectfully request withdrawal of thereof.

#### ***Rejection under 35 U.S.C. § 112, first paragraph***

In the Office Action, beginning at page 3, Claim 34 was rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matter that allegedly fails to comply with the written description requirement. Applicant respectfully requests reconsideration of this rejection.

Applicants respectfully submit that the “barrier material” recited in claim 34 is fully described by the specification, at least, in paragraph [0043]. This paragraph is descriptive of Figure 3, which shows that the luminal side 24 of the stent 10 can be provided with a barrier material 30. The intent of the barrier material, that is, to deliver the therapeutic agent to **only one side** of the stent, is fully explained in paragraph [0043], and is recited in claim 34. An example of a barrier layer is also described in Example 1, paragraph [0115].

The Office Action points to paragraph [0064]; however the Examiner misunderstands this paragraph. This paragraph further explains an embodiment of forming a matrix by diffusing drug into a matrix containing no agent. As described in paragraphs [0063] and [0064] when a barrier layer is placed in one side of the opening agent is allowed to diffuse into the matrix from primarily one side. This is simply a description of a manufacturing process and has nothing to do with the claimed delivery of the agent to one side of the implantable medical device.

When evaluating the specification for adequate written description, the full teachings in the specification must be viewed with reference to the state of the art at the time of the invention.

For at least the foregoing reasons, Applicants respectfully submit that Claim 34 fully complies with 35 U.S.C. § 112, first paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

***Rejection under 35 U.S.C. § 112, second paragraph***

In the Office Action, beginning at page 3, Claims 28, 29, and 34 were rejected under 35 U.S.C. § 112, second paragraph, as reciting subject matters that allegedly are indefinite. Applicant respectfully requests reconsideration of this rejection.

Claim 28 has been cancelled; its rejection is now moot.

Claim 29 was rejected for allegedly lacking antecedent basis for an “opening passing through the implantable medical device body”. This language has been canceled without prejudice.

Claim 34 was rejected for allegedly being confusing. The Office Action questions the “barrier layer”; however, the claim actually recites a “barrier material” which forms a “barrier” to passage of the therapeutic agent. The Examiner’s comment that the barrier layer is “to encourage diffusion” is a misunderstanding of the specification. This terminology is fully described and explained in, at least, paragraphs

[0043] and [0115] of the specification, and is described above in the response to the rejection under 35 U.S.C. §112, 1<sup>st</sup> paragraph.

For at least the foregoing reasons, Applicant respectfully submits that Claims 28, 29, and 34 fully comply with 35 U.S.C. § 112, second paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

***Rejection under 35 U.S.C. § 102***

In the Office Action, beginning at page 4, Claims 21-37 and 48 were rejected under 35 U.S.C. § 102, as reciting subject matters that allegedly are anticipated by U.S. Patent No. 5,624,411 to Tuch. Applicant respectfully requests reconsideration of this rejection.

First, the Office Action fails to address all the dependent claims and their limitations, in that these limitations are not specifically pointed to in the cited prior art as allegedly being taught by the prior art. Therefore, it is unclear why such claims and their limitations are rejected over the cited prior art. Specifically, claim 28 and the limitations recited therein, now inserted into claim 21, is not disclosed or described by the cited prior art, nor does the Office Action point to any asserted teaching of this limitation.

The stents of *Tuch* are referred to in column 4, lines 14-16. These prior art stents are typical, primitive stents having a coated outer surface and are very different from the implantable medical devices employed in the present invention. Specifically, and as shown in, at least, Figures 1, 2, 3, 6, and 9 of this application, exemplary implantable medical devices of the present invention have an opening in the form of a blind recess, or wherein the recess extends through the body of the device. The introduction of the homogenous solutions of polymer and therapeutic agent, or polymer alone, etc., of the present invention to the recess on the implantable medical device of the present invention are clearly not disclosed or described by *Tuch*, which merely describes coating an outer surface of a generic stent, and nowhere does *Tuch* disclose, describe, or suggestion

anything other than a stent outer surface that is featureless with no openings or recesses.

For at least the foregoing reasons, Applicant respectfully submits that the subject matters of Claims 21-37 and 48 are not anticipated by *Tuch*, are therefore not unpatentable under 35 U.S.C. § 102, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 102.

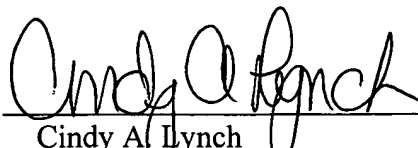
***Conclusion***

For at least the foregoing reasons, Applicant respectfully submits that the present patent application is in condition for allowance. An early indication of the allowability of the present patent application is therefore respectfully solicited.

If Examiner Silverman believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-3100.

Respectfully submitted,

By:   
Cindy A. Lynch  
Registration No. 38,699

**U.S. P.T.O. Customer No. 43027**  
1003 Hamilton Court  
Menlo Park, CA 94025  
650.614.4131

Date: September 19, 2006